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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,105	07/03/2001	Hiroyuki Ogawa	SUD-109-DIV	1178
7590 05/24/2004			EXAMINER	
Ronald R. Snider Snider & Associates P.O. Box 27613 Washington, DC 20038-7613			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/897,105

**Applicant(s)**

OGAWA, HIROYUKI

**Examiner**

Ralph Gitomer

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

The RCE request and amendment received 4/28/04 have been entered and claims 1, 2, 7 are currently pending in this application.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 7 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

The claims have been amended to include the limitation that the indicator is isolated from the medium by a CO<sub>2</sub> permeable membrane which maintains a density of CO<sub>2</sub> in the medium portion. Previously the claims included the CO<sub>2</sub> permeable membrane but not this stated function. There are two "membranes" in the apparatus, the container which contains both the medium and the indicator, and the membrane which contains the indicator only which is permeable to CO<sub>2</sub>. The container is sealed entirely from the outside atmosphere, see claim 1(d), which implies the container is impermeable to CO<sub>2</sub>. All the above is old in this art. To overcome the rejections of record, applicant has added a limitation that is inoperative. The membrane containing the indicator must be permeable to CO<sub>2</sub> because the function of the indicator is to measure CO<sub>2</sub>. However, it is not seen how the membrane containing the indicator would permit CO<sub>2</sub> to maintain CO<sub>2</sub> at the site of the microorganisms given that the container is sealed. If the microorganisms do not generate sufficient CO<sub>2</sub> to maintain the microorganisms, the membrane would have no way of providing CO<sub>2</sub> to the microorganisms.

The rejections of record of claim 1 under 35 USC 102(b) over Turner, and the rejection of record of claim 1 under 102(e) over DiGuseppi, and the rejection of claims 2 and 7 under 103(a) over each of Turner and DiGuseppi are maintained.

Applicant's arguments filed 4/28/04 have been fully considered but they are not persuasive.

Applicants argue the references do not teach a membrane that can control CO<sub>2</sub> within the medium.

It is the examiner's position that the membrane of the present invention cannot control CO<sub>2</sub> within the medium. The only possible source of CO<sub>2</sub> within the sealed container would be the microorganisms. The CO<sub>2</sub> generated by the microorganisms would pass through the permeable membrane to the indicator which would then indicate the presence of CO<sub>2</sub>. It is not seen that any CO<sub>2</sub> would pass from the indicator to the microorganisms from any source. If a significant amount of CO<sub>2</sub> passed from the indicator to the microorganisms, the indicator would not signal an accurate amount of CO<sub>2</sub> is present. If a significant amount of CO<sub>2</sub> did not pass through the membrane to the indicator, the indicator would not signal an accurate amount of CO<sub>2</sub> is present. Further, the materials from which the permeable membrane is made as disclosed in the specification as originally filed are the same materials from which the permeable membranes are made in the references cited herein.

DiGuseppi teaches in column 6 lines 44-49, the semipermeable membrane may be adjacent to the specimen and growth medium to form an integral membrane. In column 8 first full paragraph, oxygen may be provided by a gas

permeable membrane and anaerobic microorganisms may be determined. In Turner, column 7 Table 1 lists microorganisms that can be detected including *N. meningitidis* which is disclosed in the present specification as requiring CO<sub>2</sub> to be detected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

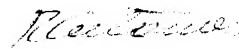
Holte (WO 93/15402) teaches CO<sub>2</sub> indicators for detecting microbial growth.

Hannan (4,513,280) teaches measuring microorganism growth by detecting CO<sub>2</sub>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer  
Primary Examiner  
Art Unit 1651

